510(k) Summary of Safety and Effectiveness

JAN 1 3 2011

This summary of 510k safety and effectiveness is being submitted in according with 21CFR part 807.92

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Date of Preparation: 2010-7-22

Proprietary Name: F2, F3 Fetal Monitor

(Models: F2, F3)

Classification Name: System, Monitoring, Perinatal

Product code: HGM, HGL

Predicate Devices:

Predicate devices	CADENCE, CADENCE DUAL, CADENCE II FETAL MONITOR
Manufacturer	Edan Instruments, Inc
K #	K082369

Device Description: With non-invasive ultrasound Doppler, external TOCO and direct fetal ECG technique, Fetal Monitor provides Non-Stress testing for pregnant women from the 28th week of gestation. You can externally monitor the fetal heart rate using ultrasound and uterine activity via a TOCO transducer. Alternatively, you can internally monitor one of the fetal heart rate with direct fetal ECG technique and uterine activity with an Intrauterine Pressure Catheter.

The Fetal Monitor has six models: Cadence, Cadence DUAL, Cadence PRO, Cadence II, F2 and F3. The former four models Cadence, Cadence DUAL, Cadence PRO, Cadence II have already been cleared under K082369, while the other two models F2, F3 are new models of Fetal Monitor in this Traditional 510(K) application, which have the same intended use and constructions to the existing models.

The Fetal monitor can be connected with Central Monitoring System via RJ45 interface. Also it can be connected to wireless network module via a DB9 interface, and the wireless network module will complete the data switch of the monitor and the Obstetrical Central Monitoring System.

Comparison with predicate device

The F2, F3 fetal monitors have the same device characteristics as the predicate approved device cleared under K082369. Both models use the same technology and circuitry as the already approved device models Cadence, Cadence DUAL, Cadence PRO, Cadence II cleared under K082369. Hence the models F2, F3 above are substantially equivalent to the predicate devices cited.

Intended Use

The F2, F3 Fetal Monitor are intended for non-invasive and invasive monitoring of fetus during antepartum examination, labor and delivery. They are intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms.

They both provide Non-stress testing for pregnant women from the 28th week of gestation. They can externally monitor the FHRs using ultrasound and uterine activity via a TOCO transducer. Alternatively, they can internally monitor one of the FHRs with DECG and uterine activity with an IUPC.

Contraindications:

It is not intended for use in intensive care units, operating rooms or for home use.

Test Summary:

The following quality assurance measures were applied to the development of the F2, F3 Fetal Monitors.

- Software testing
- Hardware testing
- Safety testing
- Environment test
- Risk analysis
- Final validation

Conclusion:

Verification and validation testing was done on the Fetal Monitor models F2, F3. This premarket notification submission demonstrates

that Fetal Monitor models F2, F3 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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APR 26 2012

Re: K102140
Trade/Device Name: Fetal Monitor model F2 and F3
Regulation Number: 21 CFR § 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM, HGL
Dated: December 20, 2010
Received: December 27, 2010

Dear Mr. Qiuhong:

This letter corrects our substantially equivalent letter of January 13, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Fetal Monitor model F2 and F3, as described in your premarket notification:

MS3-109301

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found

in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Ms. Kathryn Daws- Kopp at (301) 796-6535.

Sincerely yours,

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures

Indication for Use

510(k) Number (if known): K102140

Device Name: F2, F3 Fetal Monitors
(Models: F2, F3)

The F2 and F3 Fetal Monitor are intended for non-invasive and invasive monitoring of fetus during antepartum examination, labor and delivery. They are intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms.

They both provide Non-stress testing for pregnant women from the 28th week of gestation. They can externally monitor the FHRs using ultrasound and uterine activity via a TOCO transducer. Alternatively, they can internally monitor one of the FHRs with DECG and uterine activity with an IUPC.

Prescription Use ___X___ And/Or Over the Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K102140

Diagnostic Ultrasound indications for Use Form

Fill out one form for each ultrasound system and each transducer.

1MHz PW fetal probe

Intended use : Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows

Clinical Application	Mode Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal				P						
Abdominal										
Intraoperative(specify)										
Intraoperative Neurological										
Pediatric										
Small Organ(specify)										
Neonatal Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheraln Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

N=new indication; P=previously cleared by FDA; e=ADDED UNDER appendix E

Additional Comments: The above is a 1MHz PW transducer for the fetal heart rate detection.

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CONCURRENCE OF cdrh, Office of Device Evaluation (ODE)

Tracy The

Apr. 13, 2012